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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,829 07/14/99 SCHLIEVERT

P 600.347USWO

023552 HM12/1102
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EXAMINER

HINES, J	
ART UNIT	PAPER NUMBER

1645
DATE MAILED:

11/02/01

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/308,829

Applicant(s)
Schlievert et al.

Examiner
Ja-Na Hines

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 8, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18 20) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on August 8, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/308,829 is acceptable and a CPA has been established. An action on the CPA follows.

Amendment Entry

2. Amendments have been entered as filed on August 8, 2001. Claims 1, 3-12 and 15-23 were canceled. Claims 24-44 have been newly added. Claims 24-44 are under consideration in this office action.

Withdrawal of Rejections

3. In view of applicants remarks and amendments to the claims, the following rejections are being withdrawn:

- a) the rejections of claims 1, 3-12 and 15-23 under 35 U.S.C. 112, first paragraph; and
- b) the rejection of claim 10 under 35 U.S.C. 112, second paragraph.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a Streptococcal pyrogenic exotoxin type C (SPE-C) mutant with specifically named single and double mutations, does not reasonably provide enablement for a Streptococcal pyrogenic exotoxin type C (SPE-C) mutant with three, four or five mutations at the recited positions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 24 and 35 teach in examples five and six, single and double mutations at the recited positions, but no example teaches three, four or five substitutions at each of the recited positions. The specification only provides guidance to specific amino acids and does not teach any amino acid substitution may be changed without causing a detrimental effect to the SPE-C toxin to be produced. The claims recite a mutant that can be obtained by substituting one to five amino acids at positions 12, 15, 17, 35 or 38, if all five of the recited amino acid positions are

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substituted, the resulting mutant SPE-C could result in a mutant toxin not taught or enabled by the specification.

Furthermore, the claims do not recite whether the substitution needs to be a conservative substitution. Claims 29 and 39 are drawn to a vaccine; claims 30 and 40 are drawn to a method of protection; and claims 31, 41 and 44 are drawn to a method for reducing symptoms, yet the specification does not teach using a mutant with three or more substituted positions to work in the vaccine or recited methods. The specification only provides guidance to specific amino acids and does not teach three or more amino acid substitutions without causing a detrimental effect to the SPE-C toxin to be produced even though the positions are recited. The claim broadly recites an amino acid substitution, and no specific substitution is recited, if all the amino acids at the recited positions are substituted the resulting mutant SPE-C could result in a mutant toxin not taught or enabled by the specification.

The specification does not provide substantive evidence that the claimed vaccines which teach three or more amino acid substitutions is capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing Streptococcus infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced by any mutant of SPE-C.

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The substitution of three or more amino acids in the recited location within the mutant SPE-C would not predictably result in a stable molecule. The specification only teaches the use of single or double amino acids substitution in specific locations which result in stable variations. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which deletions, substitutions or insertions or any combination thereof would result in the desired stable, active protein. Accordingly, one of skill in the art would be required to perform undue experimentation to use any amino acid at any location to produce a stable SPE-C toxin. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.


5. Claims 24-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of “substantially nonlethal” in claims 24 and 35 is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims. The term substantially is not defined by the claims or specification such that one skilled in the art would be able to ascertain what level “substantially” would represent. Thus it is unclear what applicant intends. Clarification is required in order to this rejection.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm . The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

October 18, 2001


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600